REMARKS

Claim Amendments

Claim 1 has been amended to address the informalities cited by the Examiner and to clarify the present invention.

Claim 2 has been amended to correct a grammatical error.

Claim 18 has been amended and rewritten as an independent claim to correct dependency on now-cancelled claim 13.

Original claims 7-17 have been cancelled.

New claims 40-51 have been added in order to more clearly define the Applicant's invention. The new claims do not encompass new subject matter.

Rejections Under 35 U.S.C. §102

1.0 ***The Examiner has rejected claims 1-6 and 20-29 under 35 U.S.C. §102(e) as being anticipated by Chobotov (US 6,395,019).***

Chobotov teaches an endovascular graft (10) comprising an inflatable frame (13) having a proximal inflatable cuff (16), a distal inflatable cuff (17), an elongate inflatable channel (18) and a thin flexible layer (21) forming a lumen (22) disposed between the cuffs, through which fluid flows. The inflatable frame acts to seal the graft against an inside surface of the body passage. The endovascular graft further includes a neck portion attached to a proximal end of the lumen for biasing the proximal end and an expansion member secured to the proximal end of the inflatable frame. The expansion member is self-expanding and preferably comprises memory shape materials. On release of the expansion member from a constrained state, the member engages an inner surface of a body passage. Chobotov further discloses in column 7, line 10 that the lumen and frame are preferably made from poly(tetrafluoroethene) (PTFE) or other suitable medical polymer materials and at lines 25-28 Chobotov refers to Nitinol, a shape memory alloy, in the context of the expansion member.

The present invention teaches an implant (100) for use in obstructing flow through a blood vessel (110). The implant comprises an outer wall (102), an inner wall (104) and a cylindrical ring (130) comprising a solid material disposed between the inner and outer walls. The inner wall defines a flow passage through which blood may flow. The inner wall, outer wall and cylindrical ring may comprise memory materials or materials that absorb liquids and are capable of expanding to a final configuration thereby narrowing the flow passage of the implant. The distance between the inner wall and the outer wall of the implant is non-uniform along an axis of the flow passage. The non-uniform distance between the inner and outer wall correlates to changes in the diameter of the flow passage.

Original claim 1 has been amended to clarify the structure of the present invention. Nowhere does Chobotov teach or suggests a non-uniform distance between an inner wall and an outer wall of the channel, where the non-uniform diameter correlates to a non-uniform diameter of the lumen as recited in amended claim 1 of the present invention. Instead, the non-uniform distance between the inner and outer walls of Chobotov relates to the inflated state of the frame that encircles the lumen. The inflated frame conforms to the shape of the vessel in which the graft is disposed. As shown in Figure 2 of Chobotov, the inflatable cuff (16) includes a fluid filled chamber (41) and the inflatable channel (18) includes fluid filled chambers (42, 43). The lack of uniformity of the distance between inner and outer walls along the length of the graft has no impact on the diameter along the length of the lumen (22). The diameter of the lumen in Chobotov is constant. Applicant submits that Chobotov does not teach each of the elements recited in amended claim 1 as suggested by the Examiner and therefore Chobotov does not anticipate claim 1. Further, claims 2 - 5 depend from claim 1, therefore each of claims 2 - 5 overcome the rejections of the Examiner.

With regard to claims 26-29 of the present invention, nowhere does Chobotov teach a portion of the lumen or frame comprising shape memory materials as recited in original claim 26 as suggested by the Examiner. Instead, Chobotov suggests the lumen and frame are made of PTFE. A person skilled in the art would understand that a memory shape material could not be an equivalent to PTFE. By definition, PTFE because of its chemical inertness, cannot be cross-linked like an elastomer and therefore, PTFE has no shape memory properties. Chobotov refers to Nitinol, a shape memory alloy only in the context of the expansion member, which is not a

component of the tubular implant. Instead, the expansion member is secured to the end portion of the expandable frame and acts to further secure the entire graft within a body passageway. Clearly, Chobotov does not teach each of the elements recited in claim 26 as suggested by the Examiner and therefore, Chobotov does not anticipate claim 26. Further, claims 27 – 29 depend from claim 26, therefore each of claims 27 – 29 overcome the rejections of the Examiner.

With respect to claims 20 – 25, Applicant points the Examiner to column 8, lines 30 – 33 of Chobotov, which recite a proximal inflatable cuff (52), distal inflatable cuff (53) and an inflatable channel (54). The Examiner suggests on page 3 of the Office Action, that Chobotov teaches in Figure 4, at least one wire (52, 53, 54). Applicant respectfully submits that the Examiner has erred in the recitation of these elements, clearly Chobotov does not teach a wire. Further, on page 4 of the Office Action, the Examiner refers to "Stinson" as a reference however, the Examiner has not stated the grounds for the rejection of claims 20 – 25 in light of Stinson (US 2003/0069646), which is listed in the Notice of references cited.

Accordingly, withdrawal of this rejection is respectfully requested.

2.0 ***The Examiner has rejected claims 7 - 17 under 35 U.S.C. §102(b) as being anticipated by Perrier et al. (US 5,123,918).***

Original claims 7-17 are currently cancelled and therefore, this rejection is moot. However the Applicant submits the following arguments in support of the patentability of new claims 40-50.

Perrier et al. discloses a prosthetic heart valve having an annular base and three support flaps, where the three flaps are intended to control the flow of blood through the valve. The prosthetic heart valve of Perrier et al. is not intended nor adapted for insertion in any body passage having blood flow therethrough. Further, Perrier et al. does not teach or suggest adapting the prosthetic heart valve to act as a passageway for obstructing blood flow, specifically a passageway including a non-uniform distance between an inner and outer wall of the passageway that correlates to a non-uniform diameter along the length of the passageway.

3.0 ***The Examiner has rejected claims 13, 18 and 19 under 35 U.S.C. §102(b) as being anticipated by Latac et al. (US 2001/0010017).***

Original claim 13 is currently cancelled and therefore, this rejection is moot. However the Applicant submits the following arguments in support of the patentability of amended claim 18 and original claim 19.

Latac teaches implantable valves (IV) to repair valvular defects. Paragraphs [0074] and [0087] – [0091] of Latac describe the structure of a preferred embodiment "IV-13" comprising: an expandable rigid frame (10) having intercrossing linear bars (11) and a soft and mobile tissue constituting a valvular structure (14). The valvular structure has a continuous surface truncated between a base (15) and an upper extremity (16). The tissue of the valvular structure has rectilinear struts (17) for strengthening. Latac describes the mounting of the valvular structure onto the bars of the expandable frame as shown in Figure 2. Figures 4 and 5 of Latac illustrate the implantable valve in its compressed position, in view of its introduction and positioning in the aortic orifice, and in its expanded, opened position respectively. More specifically, Figure 5b of Latac illustrates the expanded position of the valve in a cross-sectional view along the central axis X'X of the valve prosthesis respectively.

The present invention teaches an implant for obstructing blood flow. The implant comprises a tubular wall defining a flow passage and at least one non-overlapping flap projecting from the wall of the flow passage into the blood flow, shown in Figure 2 and described in paragraphs [0057] – [0060].

Nowhere does Latac teach a tubular wall defining a flow passage as suggested by the Examiner. Instead Latac teaches a wire frame joined by bars, where the frame is for mounting of an IV. A person skilled in the art would understand the wire frame of Latac includes openings and cannot act as a flow passage. Further, Latac does not teach a flap or any means for obstructing blood flow, as suggested by the Examiner. The Examiner has misunderstood the cross-sectional view of the valve (14) shown in Figure 5b. This figure does not illustrate a flap as suggested by the Examiner. Instead, the figure illustrates a cross-sectional view of the IV (14) in the expanded position.

Latac further discloses a balloon catheter in Figure 12 and paragraph [0143] and the process for insertion of the IV using the balloon catheter in Figure 13 and paragraphs [0148]-[0152]. Figure 12 illustrates the balloon dilation catheter comprising a shaft (27f) and balloon (26). Figure 13 illustrates the steps involved in the placement of an IV utilizing the balloon dilation catheter. Clearly Latac does not teach a flap or a flap-angle adjusting tool as suggested by the Examiner. The Examiner has misunderstood the components the balloon dilation catheter and the process outlined in Figure 13.

Latac, in light of the above, clearly does not teach or suggest the elements of claim 18 of the present invention. Applicant submits that claim 18 clearly overcomes the rejections of the Examiner. In addition, as claim 19 depends from claim 18, claim 19 also overcomes the Examiner's rejection.

4.0 ***The Examiner has rejected claims 30 and 32 - 35 under 35 U.S.C. §102(b) as being anticipated by Bozzo (EP 0355341).***

Bozzo discloses a disobstructor device (1), typically for use in a urinary channel, having a tubular body (101) and a plurality of anchoring elements (2). These anchoring elements are shaped like hooks and are made of rubber or silicone resin (column 3, line 7). The hooks bend away from the body of the disobstructor device and toward the walls of a body passageway into which the device is inserted. The hooks act to anchor the device (column 3, line 36) in the body passageway. On insertion of the disobstructor device, the hooks are bent into alignment with the tubular body, as shown in Figure 8, and the free end of the hooks are inserted into a cap (20) to retain them in position an extended position for insertion. Once the disobstructor device is inserted into the body passageway a balloon (19), located below the cap, is inflated thereby releasing the ends of the hooks from the cap, as shown in Figure 9. The elasticity of the hooks causes their return to the curved position shown in Figure 9. The disobstructor device, in use, is related re-establishing patency in a urethral channel.

The present invention teaches a method of modifying the implant geometry of a tubular implant, the implant comprising at least one intra-lumen flap. The flap, when contacted by an effector element, is bent by the application of force on the flap. The effector element may be a balloon catheter as described in paragraphs [0058] and [0061]. On placement of the implant in a

body passageway, the balloon is inflated to effectively push the flap of the implant away from the walls of the body passageway and toward the longitudinal axis of the lumen, thereby reducing blood flow through the lumen.

Bozzo does not teach or disclose an intra-lumen flap, nor does Bozzo teach an effector element for contacting and bending an intra-lumen flap as suggested by the Examiner. The Examiner has misunderstood Figures 8 and 9 and incorrectly refers to the hooks of Bozzo as intra-lumen flaps. The hooks (2) of Bozzo are not configured to obstruct flow through a tubular implant, instead, the hooks act to anchor a tubular implant in a body passageway. In fact, Bozzo teaches away from the present invention as the hooks require the application of force to retain them in an extended position, as shown in Figure 8, which is counter to the present invention. The hooks of Bozzo are constructed from an elasticized material that does not require the application of force to move from the extended position of Figure 8 to the curved position of Figure 9. In the curved position, the hooks curve outwardly toward the walls of the body passageway and do not obstruct flow through the device.

Bozzo, in light of the above, clearly does not teach each of the elements of claim 30. Applicant submits that claim 30 clearly overcomes the rejections of the Examiner. Claims 32 - 35 depend from claim 30, therefore each of claims 32 – 32 also overcome the rejections of the Examiner.

Accordingly, withdrawal of this rejection is respectfully requested.

5.0 ***The Examiner has rejected claims 36 - 39 under 35 U.S.C. §102(b) as being anticipated by Andersen et al. (US 6,168,614).***

Andersen et al. teaches a valve prosthesis for implanting in the aorta using a catheter. Figure 1 of Andersen et al. illustrates a stent (1) made from surgical wires (2,3) folded into loops. Three of these loops (4) are used to secure the commissural points (5) of a valve prosthesis. Figure 2 illustrates the valve prosthesis mounted onto the stent. Figure 3 depicts a partial view of a catheter in the aorta and Figure 4 is a cross sectional view through Figure 3. The balloon (13) portion of the catheter is tri-sectional. When the balloon in expanded, as shown in Figure 3, the valve is also expanded and is in contact with the walls of the aorta (column 5, line 35).

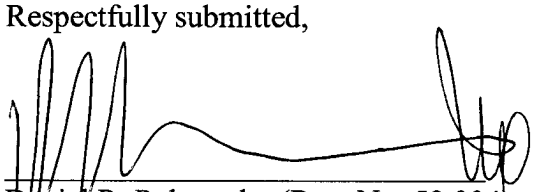
The present invention teaches an implant having a radially expandable tubular sheath having at least one flap welded to the sheath to at least partially obstruct the lumen of the sheath. The implant further includes at least one restraining element interconnecting a pair of flaps and limiting their movement in relation to one another.

Applicant submits that the Examiner has misunderstood Figures 1 and 4 of Andersen et al., which clearly do not teach a flap (4) or a restraining element (13). Andersen et al. clearly discloses in column 4, line 66 through column 5, line 4, a stent made of steel wires where the wires are folded into loops (4). Andersen et al. further discloses in column 5, lines 33-35 a tri-sectional balloon means (13) onto which the valve prosthesis is placed and then inserted into a passageway. Nowhere does Andersen et al. teach or suggest modifying the valve prosthesis to include a flap or restraining element as taught by the present invention.

Andersen et al., in light of the above, clearly does not teach a flap that is welded to an expandable sheath nor a restraining element as taught by the present invention. Therefore, Andersen et al. does not anticipate claim 36. Each of claims 37-39 depend from claim 36 and include all the limitations of claim 36, as such, Andersen et al. does not anticipate claims 37-39.

In view of the above amendments and comments, the applicant submits that pending claims 1-6 and 18-51 are patentable. Favorable reconsideration and allowance of this application are respectfully requested.

Respectfully submitted,

By: 

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